K130877

510(K) SUMMARY

JUN 2 0 2013

A. Submitter Information

Manufacturer:	Medos International Sárl Chemin-Blanc 38 2400 Le Locle, Switzerland
Submitter:	DePuy Spine, Inc. 325 Paramount Drive Raynham, MA 02767
Contact Person:	Kirsten Lehmuller 325 Paramount Drive Raynham, MA 02767
Telephone number:	508-828-3291
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B. Date Prepared March 27, 2013

C. Device Name

Trade/Proprietary Name:	EXPEDIUM® Spine System
Common/Usual Name:	Pedicle screw spinal system
Classification Name:	Spinal interlaminar fixation orthosis per 21 CFR §888.3050, KWP Spinal intervertebral body fixation orthosis per 21 CFR §888.3060, KWQ Pedicle screw spinal fixation per 21 CFR §888.3070, MNH, MNI, NKB, OSH

D. Predicate Device Name

Trade name: EXPEDIUM® Spine System (K041119)
EXPEDIUM® Spine System (K062174)
EXPEDIUM® Spine System (K071495)
EXPEDIUM® Spine System (K073364)
EXPEDIUM® Spine System (K082942)
EXPEDIUM® Spine System (K090230)
EXPEDIUM® Spine System (K101070)
EXPEDIUM® Spine System (K111136)

E. Device Description

The subject additions to the EXPEDIUM 4.5mm, 5.5mm, and 6.35mm Spine Systems consist of open angled extended, slotted connectors and various rods. The connectors are available in titanium alloy with lengths of 5, 10, 15, and 20mm. The rods vary in size and geometries to accommodate patient anatomy and are available in materials of titanium, stainless steel, and cobalt chrome.

F. Intended Use

The EXPEDIUM Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The EXPEDIUM Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the EXPEDIUM System metallic implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The EXPEDIUM system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The proposed modifications to the EXPEDIUM open extended, angled slotted connector is similar to the predicate (K101070) except the head/rod interconnection is open rather than closed, like the predicate monoaxial screw (K062174). The proposed EXPEDIUM rods are similar to the predicates (K041119, K062174, K071495, K082942, K090230, and K101070) except for the varying lengths and slight modifications to the geometry.

G. Materials

Manufactured from ASTM F 138 implant grade stainless steel, ASTM F 136 implant grade titanium alloy, and ASTM F 1537 implant grade cobalt -chromium-molybdenum alloy.

H. Performance Data

Performance data per ASTM F 1798 were submitted to characterize the subject EXPEDIUM Spine System connector addressed in this notification. This testing was compromised of static axial slip and both static and dynamic cantilever beam bending. A rationale is provided in place for performance testing for the subject rods of this submission.

I. Conclusion

Both the Performance Testing and Substantial Equivalence Justification demonstrate that the subject devices are as safe, as effective, and perform as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 20, 2013

Medos International, Sárl
% DePuy Spine, Incorporated
Ms. Kirsten Lehmuller
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K130877
Trade/Device Name: EXPEDIUM® Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Codes: NKB, OSH, MNH, MNI, KWP, KWQ
Dated: April 4, 2013
Received: April 5, 2013

Dear Ms. Lehmuller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130877

Device Name: EXPEDIUM® Spine System

Indications For Use:

The EXPEDIUM Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

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Prescription Use ___X___ AND/OR Over-The-Counter Use ___ ___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130877